P/ ENT COOPERATION TREAT

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 25 November 1999 (25.11.99)	
International application No. PCT/US99/06187	**Applicant's or agent's file reference** HKZ-029CPPC
International filing date (day/month/year) 19 March 1999 (19.03.99)	**Priority date** (day/month/year) 19 March 1998 (19.03.98)
Applicant SIM, Gek-Kee et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

19 October 1999 (19.10.99)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Kiwa Mpay
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PATENT COOPERATION TREATY

REC'D 09 JUN 2000
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
HKZ-029CPPC		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US99/06187	19/03/1999	19/03/1998
International Patent Classification (IPC) or national classification and IPC C07K14/00		
Applicant HESKA CORPORATION et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19/10/1999	05.06.2000
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Giebeler, K Telephone No. +49 89 2399 8546

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/06187

I. Basis of th report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

Description, pages:

1-73 as originally filed

Claims, No.:

1-39 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-14,16-20,22,23,25-31,33-39(all partitially); 15,21,24,32(totally).

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 7(partially) are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☒ the claims, or said claims Nos. 7(partially) are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1-14,16-20,22,23,25-31,33-39(all partially); 15,21,24,32(all totally).

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3,5-9,18,20,22,23,25,29,30,33-39
	No:	Claims	1,2,4,10-14,16,17,19,26-28,31
Inventive step (IS)	Yes:	Claims	
	No:	Claims	3,5-9,18,20,22,23,25,29,30,33-39
Industrial applicability (IA)	Yes:	Claims	1-6,8-39
	No:	Claims	7

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Examination has only been carried out for subject-matter for which a search report has been established, i.e. claims 1-14, 16-20, 22, 23, 25-31 and 33-39 as far as they relate to the canine B7-1 protein.

   Furthermore, claim 7 has not been examined with respect to the "mimetope" as defined on page 18, lines 18-21, because this subject-matter is neither clear nor supported by the description. Said term includes any molecule exhibiting one of the activities of B7 and is not limited to the canine protein. It is impossible to determine the exact scope of the claims.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. The following documents are cited:

   D1= EMBL accession number U57755, Sequence identity g2065520, 20-5-1996, Felis catus T-cell specific surface glycoprotein B7-1 mRNA XP002107312 cited in the application & HASH, S.M.: THESIS, VETERINARY PATHOLOGY,1996, TEXAS A & M cited in the application

   D2= YANG, S. ET AL.: 'Cloning of genes encoding canine co-stimulatory molecules' FASEB JOURNAL FOR EXPERIMENTAL BIOLOGY, vol. 12, no. 5, 20 March 1998 (1998-03-20), page a940 XP002107311 BETHESDA, MD US & Annual Meeting of the Professional research scientists on experimental biology 98, part II San Francisco, USA, April 18-22 1998

3. The current assessment is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. If it later turns out that this is not correct, the document D2 cited in the international search report would become relevant.

4. The present application does not satisfy the criterion set forth in Article 33(1)(2) PCT because the subject-matter of claims 1, 2, 4, 10-14, 16, 17, 19, 26-28 and 31 is not new.

   The document D1 discloses the sequence of a nucleic acid encoding feline B7-1 and the encoded protein, said nucleic acid being 84.1% identical to the one of SEQ ID NO:1. The document is thus prejudicial to the novelty of at least claims 1, 2, 4, 10-14, 16, 17, 19, 26-28 and 31. The sequence of D1 is furthermore novelty-destroying since it comprises stretches of 12 and more nucleotides of SEQ ID NO:1. It should furthermore be noted that the terms "at least about 80%" and "at least about 12" are in any case unclear the can therefore not be used to distinguish the claimed matter from the prior art, for instance from other known B7-1 proteins from human, rhesus monkey, rabbit or mouse (see page 2, paragraph 2 of the description).
   Claim 19 furthermore lacks novelty over nearly any mammalian cell which naturally contains the B7-1 gene. The term "recombinant" does not define a distinguishing feature. Moreover, recombinant mammalian cells are generally known.

5. The present application does not satisfy the criterion set forth in Article 33(3) PCT because the subject-matter of claims 3; 5-9, 18, 20, 22, 23, 25, 29, 30, 33-39 does not involve an inventive step.

   Claims 3, 5, 20, 22, 23, 25, 30 and 33-36 relate to soluble forms of canine B7-1 protein. However, it is well within ordinary skill in the art to delete part of the hydrophobic region of a protein in order to obtain a soluble form thereof.
   Claims 6-9 and 37-39 are considered to lack an inventive step since it would have been obvious for a skilled person to produce the B7-1 protein by applying standard techniques and to use it in therapy and diagnosis.
   It is also standard practice to raise antibodies, and claim 29 therefore lacks an inventive step. Concerning claim 18, it is common practice to express protein in recombinant viruses.

6. For the assessment of the present claim 7 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VIII
Certain observations on the international application

7. The application does not meet the requirements of Article 6 PCT because claims 1, 2, 4, 6-14, 16, 26-28 and 37-39 are not clear.

The term "about" used throughout the claims renders the claims unclear.

In claims 13, 14 and 28, the term "allelic variation" renders the scope of these claims unclear. The definition of this term given on page 14, lines 1-5 is also unclear and not suitable to distinguish the claimed subject-matter from the prior art.

Claim 12 is unclear since the meaning of the arbitrary designations used therein were not know by and therefore unclear to persons skilled in the art at the priority date of the application.

Claims 10-14, 16, 27, 28, 37 and 38 are unclear as to their category since these claims merely refer to "the invention of claims...".

Claims 26 refers to a nucleic acid molecule of claims 1-3 and 6-8, although claims 6-8 are not directed to nucleic acid molecules.